

# Office Action Summary

Application No.

09/786,253

Applicant(s)

ROWE ET AL.

Examiner

Ginny Portner

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 05 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-52 is/are pending in the application. *Canceled*
- 4a) Of the above claim(s) 32-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-23, 25-32 and 52 is/are rejected.
- 7) ☐ Claim(s) 4, 5, 9, 12, 13, 24, 26-28 and 30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

4, 6, 7  
13, 14  
24-51  
canceled

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

37. Claims ~~1-4, 6-14~~ are rejected under 35 U.S.C. 102(b) as being anticipated by Leer et al

(WO97/14802).

*Non-Slime producing*

Leer et al disclose the instantly claimed invention directed to compositions that comprise a fragment of a lactic acid producing microorganism, specifically a 29 kDa bacterial protein from *Lactobacillus fermentum* 104R (see page 17, lines 15-16), and peptide fragments thereof (see page 23, paragraph v) and page 25, lines 13-24). The protein or polypeptide induces an immune response as it immunoreacts with polyclonal and monoclonal antibodies (see page 30, claim 13).

The protein, polypeptide or fragment was disclosed and claimed to be in combination with a pharmaceutically acceptable dosage form (see claim 29, page 33), which includes forms for topical, oral, intravenous administration (see page 10, lines 31-39 and page 11, lines 1-3).

The disclosed pharmaceutical compositions (see page 11, lines 28-31) are for administration to a vertebrate (human, pig, mouse, see all examples).

The disclosure teaches a method of improving food products the importance of administering the composition to interfere with adhesion of gastrointestinal, urogenital, oral, nasal and respiratory pathogens (see page 8, lines 7-15).

*1, 8, 9, 12, 16, 18, 19, 21*

The disclosed adhesion protein serves to combat bacterial infections associated with Clostridium (see page 10, lines 5- 22 (Clostridium, being a gram positive microorganism)) and is therefore a Clostridium-like strain of Lactobacillus which produces a protein or polypeptide which serve to prevent undesired effects caused by Clostridium-like strains of microorganism through preventing colonization by blocking adhesin to host cell receptors.

The reference anticipates the instantly claimed compositions that comprise a fragment or fragments of a Clostridium like species. The recited intended use of the claimed invention does not distinguish over the applied prior art, because the microorganism fragment was obtained and formulated into a composition from a lactic acid producing microorganism, and is able to prevent the first step of infection through blocking mucosal colonization of pathogenic microorganisms (see entire abstract).

38. Claims 1-23, ~~25-32~~ and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by (WO99/00136 ; publication date January 7, 1999).

(Instant claims 1-7, 9-15) WO99/00136 disclose compositions which comprise whole living cells of Bacteroides-like species, Selenomonas species (see page 43, claim 14), Enterococcus (see page 43, claim 18), Streptococcus species (see page 43, claim 18; specifically Streptococcus bovis: see page 43, claims 19-20), as well as additional probiotic strains of bacteria (see page 43, claim 14), singularly or in combination (see page 7, line 11), to include adjuvants, specifically cytokine adjuvants (see page 11, line 9) and an active agent (see glycopeptide, page 4, lines 21-28).

(Instant claim 8) The compositions are formulated as vaccines (veterinary or pharmaceutical compositions (see page 7, line 17) for administration by intra-muscular or sub-

18  
19, 17  
22 20 16  
21 15  
1, 2, 8, 9, 10, 12,  
dm

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cutaneous injection (see page 11, paragraph 3). (Instant claim 52: in light of the rejection under 35 USC 112, second paragraph with respect to the presence of brackets in the claim, and the deposit requirements under the Budapest treaty not being perfected) WO 99' anticipates isolated cultures of the recited microorganisms in claim 52 (see page 7, lines 3-4, page 6, line 35; see page 10, lines 36-38; page 11, lines 1-13).

(Instant claims 16-20, ~~25-30~~) WO99/00136 disclose the instantly claimed invention to a method for the treatment and/or prophylaxis of lactic acidosis in a vertebrate, the method comprising the step of

immunizing (see page at least page 11, lines 25-30) or administering to said vertebrate a therapeutically effective amount of a vaccine (see pages 4-11; especially page 6, lines 35-37; page 7, lines 10-11 ) in combination with additional active agents); the active agent is an "antibiotic, enzyme preparations, clay preparations, compounds which slow the digesta flow rate and probiotic preparations (see page 41, claims 2-14)", and an adjuvant (the adjuvant being a cytokine, see page 11, lines 9-10). Active agents are disclosed at pages 4, lines 16-38 through page 6, lines 1-16). (Instant claims 31-32) The compositions also includes probiotic bacterial preparations of Megasphaera, Veillenolla, Selenomonas, Propionibacterium, Anaerovibrio and Peptococcus (see page 7, lines 2-4) which may be used individually, or in combination together (see page 7, line 4-11).

(Instant claims 21-23) The reference also discloses the claimed method for the treatment and/or prophylaxis of lactic acidosis in a vertebrate, the method comprising the step of :

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administering to said vertebrate a therapeutically effective amount of an active agent (see abstract) capable of preventing or controlling lactic acid accumulation in the gut of the vertebrate (see all claims, pages 41-44), wherein the active agent is an "antibiotic, enzyme preparations, clay preparations, compounds which slow the digesta flow rate and probiotic preparations (see page 41, claims 2-14).

39. Claims 1-4, 7, 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayashi et al (US Pat. 4,906,612) as evidenced by US Pat. 6,429,006.

Hayashi et al disclose a composition that comprises a fragment of a microorganism, the microorganism fragment being a glycopeptide (see col. 1, lines 5-6) isolated from *Bacillus subtilis* (see col. 4, lines 25-27), a lactic acid producing bacteria (as evidenced by US Pat. 6,429,006 : "the genera *Lactobacillus*, *Bacillus* and *Rhizopus* produce L (+) -lactic acid."); *Bacillus subtilis* being like the recited bacterium through production of lactic acid. The glycopeptide serves to promote growth of animals (see title, col. 2, lines 27-42), including sheep, goats, cows, pigs, chickens, turkeys, ducks, rabbits and domestic animals (see col. 3, lines 22-27) through improved feed utilization efficiency (see col. 3, lines 39-41). The reference anticipates the instantly claimed invention.

40. Claims 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Leedle et al (US Pat 5,380,525) . Please Note: the examiner is reading the phrase "active agent" to encompass any agent with the recited functional characteristics.

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Leedle et al disclose a method for the treatment and/or prophylaxis of lactic acidosis in a vertebrate, the method comprising the step of:

administering to said vertebrate a therapeutically effective amount of an active agent (a biologically pure bacterial culture of *Megasphaera elsdenii*, see col. 2, lines 15-22; lines 26-31) capable of preventing or controlling lactic acid accumulation in the gut of the vertebrate (see Leedle et al, title, claim 4). The reference anticipates the instantly claimed method.

**Conclusion**

41. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure and are considered to be duplicative of the art applied against the claims above:

42. Argoudelis et al (US Pat. 5,981,234; US Pat. 5,695,984); Baylis et al (US Pat. 4,393,046); Ishihara et al (US Pat. 4,276,286); Garner et al (US Pat. 5,529,793) Gillin et al (US Pat. 4,237,116); Huber (US Pat. 4,112,069) Muir et al (US Pat. 4,061,732, control of lactic acidosis in ruminants); Reid et al (US Pat 6,613,549); Spangler et al (US Pat. 6,524,574); Spries (US Pat. 4,394,377); Ware et al (US Pat. 5,534,271).

43. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703) 308-7543. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703)308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

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Vgp

January 22, 2004

*L.F.S.*  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
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~~abbreviations in the claims is permitted upon the definition of the abbreviation in the claims at its first appearance. Appropriate correction is required.~~

***Claim Rejections - 35 USC § 112***

17. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

18. Claims 2-3, 10, 11, 22, 23 and 52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for various compositions that comprise the recited bacteria, does not reasonably provide enablement for the specific isolate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use novel strains with unobvious characteristics the invention commensurate in scope with these claims.

The claims are directed to specific strains and species of microorganism, that need a perfected deposit in order to enable the claimed invention. For each deposit made pursuant to the Budapest Treaty regulations, shall contain:

- (1) The accession number for the deposit;
- (2) The date of the deposit;
- (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
- (4) The name and address of the depository.
- (e) Any amendment required by paragraphs (d)(1), (d)(2) or (d)(4) of this section



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must be filed before or with the payment of the issue fee (see § 1.312).

[Added, 54 FR 34882, Aug. 22, 1989, effective Jan. 1, 1990; paras. (b) and (c)

revised and para. (e) added, 66 FR 21092, Apr. 27, 2001, effective May 29, 2001]

This rejection can be obviated through perfection of the Deposit and amendment of the claims to clearly set forth the Deposited strains.

19. Claim 1-23, 25-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for whole living compositions of microorganisms that reduce lactic acidosis, specific agents that reduce lactic acidosis conditions, and specific immunogens that will induce an immune response that will specifically inhibit the production of lactic acidosis does not reasonably provide enablement for any fragment or fragments of any of the recited microorganisms to function as a vaccine or pharmaceutical component of a pharmaceutical composition administered to an animal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification fails to teach how to formulate and use the claimed vaccines that comprise any fragment or fragments of a microorganism. The term "vaccine" encompasses the ability of the specific antigen to induce protective immunity against the lactic acidosis causing microorganism, thus preventing infection and/or disease induction.

The specification does not provide substantive evidence that any fragment or fragments of any of the recited microorganism can function as vaccines or pharmaceutical compositions that are capable of inducing protective immunity in the claimed methods. This demonstration is required for the skilled artisan to be able to use the claimed vaccines for their intended purpose

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of preventing lactic acidosis. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed vaccines that comprise any fragment or fragments of the recited microorganism, i.e. would not be able to accurately predict if protective immunity has been induced.

The ability to reasonably predict the capacity of a single bacterial immunogen to induce protective immunity from in vitro antibody reactivity studies is problematic. Ellis exemplifies this problem in the recitation that "the key to the problem (of vaccine development) is the identification of the at protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies"(page 572, second full paragraph). Unfortunately, the art is replete with instances where even well characterized antigens that induce an in vitro neutralizing antibody response fail to elicit in vivo protective immunity. See Boslego et al. wherein a single gonococcal pillin protein fails to elicit protective immunity even though a high level of serum antibody response is induced (page 212, bottom of column 2). Accordingly, the art indicates that it would require undue experimentation to formulate and use a successful vaccine without the prior demonstration of vaccine efficacy.

The specification fails to teach the identity the claimed fragment or fragments compositions with the claimed characteristics, i.e. capable of treating lactic acidosis. Further, the specification fails to provide an adequate written description of the genus of fragment or fragment containing vaccine/pharmaceutical composition that serve the recited intended use, the skilled artisan would be required to de novo locate, identify and characterize the claimed other proteins. This would require undue experimentation given the fact that the specification is completely lacking in teachings as to other surface proteins with the claimed characteristics.

20. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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21. Claims 1-23, 25-32 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

22. Claims 1-23, ~~25-32~~ and 52 recite the phrase "wherein in said microorganism is capable of producing lactic acid within the gut of said vertebrate". In view of the fact that the claimed vaccine is for prevention of lactic acidosis and the claimed microorganism produce lactic acid, it appears that the microorganisms in the vaccine would cause the problem rather than prevent it.

Clarification of the recited intended use "prevention of lactic acidosis" of the vaccine is requested.

23. Additionally, claims 1-23, 25-32 and 52 recite the phrase "fragment or fragments" that are in a vaccine, the vaccine being able to prevent lactic acidosis; what are the claimed fragments? As the structure or biological function of the fragments which evidence the recited capability is not set forth in the claims. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

24. Claims 1-23, 25-32 and 52 recite the term "like". The American Heritage Dictionary of English, Fourth Edition, 2000, defines the term like to mean "possessing the characteristics of; resembling closely; similar to." The term "like" in claims 1-23, 25-32 and 52 is a relative term which renders the claim indefinite. The term "like" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the

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art would not be reasonably apprised of the scope of the invention. What characteristic or characteristics is required to function as a vaccine in the claimed microorganism, fragment or fragments of the microorganisms that are like the recited bacteria is unclear.

25. Claims 3, 11, 23 and 52 recites various abbreviations, the abbreviations being set apart from the claim limitations in brackets. What the scope of the recited terms in brackets is unclear

and what the meaning of the recited abbreviated terms set forth is also unclear. What is the scope of the claims? The meets and bounds of the claims which recite the abbreviations and brackets can not be ascertained as it is not clear whether what is set off by the brackets is apart of the claim or not. Claim 6 recites the phrase "outer membrane and associated proteins"; this phrase

lacks antecedent basis in claim 1 from which it depends. Amendment of claim 6 to recite— wherein said fragment or fragments comprises outer membrane and associated proteins of said microorganisms—or an equivalent phrase similar to the claim limitations set forth in claim 7.

27. Regarding claims 7 and 14, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

28. Claim 13 recites "wherein the microorganism" "is present as outer membrane and associated proteins". A microorganism is made of many different parts and proteins, but the individual parts or proteins is NOT the microorganism. According to Stedmann's Medical dictionary, the term "microorganism" is : A microscopic organism (plant or animal). A outer membrane and associated proteins is not a microorganism. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so

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as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "outer membrane and associated proteins" in claims 12-13 is used by the claim to mean "microorganism", while the accepted meaning is "microscopic plant or animal." The term is indefinite because the specification does not clearly redefine the term.

29. Claims 20-23 recites the phrase "an active agent". The activity of the active agent is not defined, by any specific structure or known biological function. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

30. Claims 27-29 recite the term "bacteria"; this term lacks antecedent basis in claim 25 which recites the term microorganism.

31. Claim 25 recites the term "active agent" and depends from claim 19 which recites the limitation "microorganism"; there is insufficient antecedent basis for this limitation in claim 19; claim 25 broadens the scope of claim 19 by redefining what is administered.

32. Claim 26 defines the antibiotics to be active against gram positive microorganisms, and indirectly depends from claims 1 and 10 which also recite gram negative microorganisms. . It is unclear how the active agent of claim 26 corresponds to the recited gram negative bacteria in the compositions set forth in claims 1 and 10. How claim 26 is further limiting of the genus of gram negative compositions defined in claims 1 and 10 is unclear.